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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,065	05/26/2006	Yoav Kimchy	50499-00001	1417

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MARSH, FISCHMANN & BREYFOGLE LLP
8055 East Tufts Avenue
Suite 450
Denver, CO 80237

EXAMINER	
NGUYEN, HIEN NGOC	
ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,065	KIMCHY, YOAV	
	Examiner	Art Unit	
	HIEN NGUYEN	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-155* is/are pending in the application.

4a) Of the above claim(s) *1-122* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *123-155* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05/26/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 123-125, 128-136, 138-139, 142-143, 144-151 and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by Kimchy et al. (US 2003/0139661).

Regarding claims 123-125, and 128 Kimchy discloses a capsule, adapted to be swallowed by a subject comprising:

- photon detector to detect radiation; (see [0109-0114], abstract and claim 2).
- a radiopaque oral contrast agent use for marking and identification; (see [0109-0114], [0356] and claim 79).
- a control unit for control data and operation; (see [0109-0114] and claim 1);
- a radiation source for transmitting radiation to gastrointestinal tract; (see [0081]).
- the radiation source comprises a radioisotope; (see [0094] and [0354]).

Regarding claim 129-136, Kimchy discloses:

- control unit is capable of analyzing x-ray fluorescence photons generated responsively to the emitted radiation and Compton backscattered photons generated responsively to the emitted radiation; (see abstract, claim 2 and [0081]). Kimchy's device has a nuclear detector and can include a radiation emitter therefore it can detect x-ray fluorescence photons and Compton backscattered photons. Compton scattering are photons created from x-ray when it interact with matter.
- the control unit is capable of adapting to estimate a distance from a site of the capsule to a wall of the GI tract; (see abstract and [0081]).
- the control unit is capable of adapting to estimate the distance by estimating a depth of the contrast agent between the site of the capsule and the wall of the GI tract responsively to the analysis of the Compton backscattered photons; (see abstract and [0049]).
- the radiation source is capable of adapting to emit the radiation from the capsule only a portion of a time that the capsule is in the GI tract; (see abstract and [0081]).
- a sensor is capable of adapting to sense a parameter indicative of possible imminent motion of the capsule in the GI tract, and the radiation source can be adapted to emit the radiation from the capsule responsively to the sensing of the parameter by the sensor; (see abstract and [0081]).

Regarding claims 138 and 139, Kimchy discloses:

- a balloon for inflating around the capsule; (see [0010]).
- photon detector to detecting incoming photons; (see claim 2).

Regarding claims 142 and 143, Kimchy discloses:

- clinically-relevant feature includes a pathological abnormality of the GI tract and the pathological abnormality includes a polyp; (see abstract and [0004]).

Regarding claims 144-151, Kimchy discloses:

- the control unit is capable of adapting to detect that the capsule has reached an area of clinical interest within the GI tract; (see abstract, claim 1 and [0081]).
- the control unit is capable of adapting to withhold the emission of radiation by the radiation source until the capsule has reached the area of clinical interest; (see claim 1 and [0081]).
- the control unit is capable of adapting to withhold the photon detector from detecting photons, and to withhold the control unit from analyzing data, until the capsule has reached the area of clinical interest; (see abstract, claim 1 and [0081]).
- the control unit is capable of adapting to detect that the capsule has reached the area by detecting and analyzing X-ray fluorescence photons; (see abstract, claim 2 and [0081]).
- the capsule is capable of including a pressure sensor and the control unit can be adapted to detect that the capsule has reached the area

responsively to a change in pressure detected by the pressure sensor; (see [0081]).

- The control unit is capable of adapting to withhold the emission of radiation by the radiation source until the capsule has reached the area of clinical interest; (see abstract, claim 2 and [0081]).
- the control unit is capable of adapting to detect that the capsule has reached the area by detecting and analyzing X-ray fluorescence photons and responsively to the change in pressure; (see abstract, claim 2 and [0081]).

Regarding claim 155, the device in claim 123 disclose by Kimchy performs the method steps in claim 155 therefore it is rejected for the same reason as in claim 123.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 126-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimchy et al. (US 2003/0139661) in view of Sato (EP 0390478 A1 (provided in the IDS)).

Regarding claims 126 and 127 Sato discloses:

- at least one collimator adapted for collimate the radiation emitted by the radiation source or collimate the photons detected by the photon detector for a more accurate detection of the photons; (see abstract and col. 1, lines 1-52).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kimchy's device with a collimator to collimate radiation or collimate the photons taught by Sato because with a collimator Kimchy's device can accurately direct the transmission of radiation to the target area and detect the scattering photon with higher efficiency.

5. Claims 137 and 140-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimchy et al. (US 2003/0139661) in view of Gazdzinski (US 2001/0051766).

Kimchy substantially disclose all claim limitations set forth in claim 135. However he does not disclose a shield, and an actuator to move radiation source and the shield so the shield does not block the radiation emitted from the radiation source during the portion of the time. Gazdzinski discloses:

- a shield to block radiation; (see [0238-0240]).
- an actuator configured to close or retract the shield so that the shield can block or allow the radiation emitted from the radiation source; (see [0238-0240]).

It would been obvious to one skill in the art to modify Kimchy's device to include a shield and an actuator that retract the shield taught by Gazdzinski because with a moving shield the system can block radiation from reaching healthy tissue or allow radiation to past from the source to the target treatment.

6. Claims 152-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimchy et al. (US 2003/0139661) in view of Kim et al. (US 6,719,684).

Kimchy substantially discloses all claim limitations set forth in claim 123. However, he does not disclose extending element adapted to maintain the capsule a certain distance from a wall of the GI tract and orient the capsule parallel to a longitudinal axis of the GI tract. Kim discloses:

- extending element adapted for maintaining the capsule a certain distance from a wall of the GI tract and orient the capsule parallel to a longitudinal axis of the GI tract; see Kim col. 4, lines 15-49, col. 5, lines 1-50 and Fig. 1A-2D.

It would have been obvious to one skill in the art at the time of the invention to modify Kimchy's device to have extending element to maintain the capsule a certain distance from a wall of the GI tract and orient the capsule parallel to a longitudinal axis of the GI tract taught by Kim because the extending element allows the capsule to maintain a certain distance from a wall of the GI tract and orient the capsule parallel to a longitudinal axis of the GI.

7. Claim 154 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kimchy et al. (US 2003/0139661), in view of Kim et al. (US 6,719,684) and further in view of Park et al. (US 2001/0038831).

Kimchy and Kim substantially disclose all claim limitations set forth in claim 153. However, they do not disclose super absorbent hydrogel that expand when the hydrogel absorbs liquid from the GI tract. Park discloses:

- a super absorbent hydrogel that expand when absorb liquid; (see [0021]).

It would have been obvious to one skill in the art at the time of the invention to modify Kimchy's device to include super absorbent hydrogel taught by Park because when the hydrogel absorb liquid from the GI tract it expand and this expansion keep the capsule a certain distance from a wall of the GI tract.

Response to Arguments

Applicant's arguments filed 05/18/2009 have been fully considered but they are not persuasive. Applicant argued Kimchy does not teach or suggest a radiopaque oral contrast agent as part of the apparatus for practicing his invention. Applicant also argued Kimchy discloses a different type of contrast agent. Kimchy discloses MRI contrast agents (see [0243]). MRI contrast agent is the same as radiopaque agent. Kimchy discloses the use of contrast agent in his invention (see [0109-0114] and claim 79, especially claim 79). Examiner interprets this as Kimchy discloses radiopaque oral contrast agent as part of the apparatus for practicing his invention. In the claim applicant is not clear on what is considered part of the apparatus. Does it has to be connected or

inside an object to be considered part of the apparatus? The claim is "a radiopaque oral contrast agent, adapted to be administered to the subject" Kimchy discloses contrast agent administered to the subject therefore it meet claim limitation. Applicant argued Kimchy does not disclose high Z radiopaque contrast agent. Kimchy discloses iodine agent (see [0356]). Iodine is a high Z contrast agent. Applicant argued Kimchy does not disclose limitations to claims 132-134. Examiner disagree because the apparatus disclose by Kimchy is capable of performing the functions in these claims. Claims 132-134 claim a control unit adapted to perform these functions. Kimchy's apparatus is capable of adapting to perform these functions. Kimchy's data handling apparatus is capable of processing and analyzing detected radiation and Kimchy's device has a nuclear detector to detect x-ray fluorescence photons and Compton backscattered photons (see claims 1 and 2). Compton scattering are photons created from x-ray when it interact with matter. Kimchy's device detects radiation, after it detects radiation it has to process and analyze it therefore the system inherently has a processor in the data handling apparatus to perform this function. Processing and analyzing radiation is similar to analyze Compton backscattered and X-ray fluorescence photon there is no reason why the processor can not be adapted to perform these analysis. Also the applicant argued Kimchy does not disclose a control unit is adapted to estimate the distance base on Compton backscattered and X-ray fluorescence. Examiner disagrees because the system discloses by Kimchy is capable of adapting to analyze Compton backscattered and X-ray fluorescence photon and it is capable of estimating the distance base on photon (see claims 11 and 12). Detect photon, analyze the detected

time and the detect energy would give the distance. Kimchy discloses radiation detector and data handling/processing unit, it has all the components to analyze Compton backscattered and X-ray fluorescence photon to estimate the distance.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768